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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,838	02/21/2002	Tania C. Sorrell	1274/62620/PJP	4331

7590 09/30/2004

EXAMINER

CLOW, LORI A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/081,838	SORRELL ET AL.
	Examiner	Art Unit
	Lori A. Clow, Ph.D.	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 July 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-54 is/are pending in the application.
 - 4a) Of the above claim(s) 10-14, 28-32 and 46-50 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-9, 15-27, 33-45 and 51-54 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 1 Oct. 2003.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Applicant's election without traverse of species A directed to bacteria in the reply filed on 21 July 2004 is acknowledged.

Claims 1-9, 15-27, 33-45, and 51-54 are elected. Claims 10-14, 28-32, and 46-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species. Election was made **without** traverse in the reply filed on 21 July 2004.

Applicant is reminded that upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Objections to the Specification

The disclosure is objected to because of the following informalities: on page 5 at line 7, the word "identification" is misspelled. Appropriate correction is required.

Information Disclosure Statement

The Information Disclosure Statement filed 1 October 2003 has been partially considered. References 29 and 60 have been lined through, as copies of these references were not included with the IDS. A signed copy of PTO Form 1449 is included with this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 15-27, 33-45, and 51-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "maximally" in claims 1, 19, and 37 is a relative term which renders the claim indefinite. The term "maximally" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Is it the area, for example, that best represents spectra from a particular sample or a set of samples? Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6-9, 17, 37, 42-45, and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Himmelreich et al (MAGMA (2000) Vol. 11, Suppl. 1, page 199).

Himmelreich et al. teach a MR spectroscopy method to identify metabolites that distinguish between microorganisms and classify them by multivariate analysis. In regard to

claims 1 and 37, Himmelreich et al. teach obtaining magnetic resonance spectra (paragraph 1), decomposing spectra into integral regions (paragraph 2), and classifying using cross-validation and linear discriminant analysis (paragraph 3).

In regard to claims 6-9 and 42-45, Himmelrich et al. identify 28 species of bacteria, including *Staphylococcus*, *Enterococcus*, and *Streptococcus* species (paragraph 2).

In regard to claims 17 and 53, the specimens were from cultured bacteria (paragraph 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, 15-27, 33-45, and 51-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Somorjai et al. (Magnetic Resonance in Medicine (1995) Vol. 33, pages 257-263; PTO Form 1449 Reference 21), in view of Delpassand et al. (Journal of Clinical Microbiology (1995) May, page 1258-1262; PTO Form 1449 Reference 5).

In regard to claims 1-5, 19-23, and 37-41 Somorjai et al. teach obtaining magnetic resonance spectra from biomedical samples (page 257, column 2), subdividing regions into subregions (page 258, column 1), developing classifiers for training sets, and using cross validation on the training sets, and allocating members of a test set to a certain class (page 258, column 2). The procedure is repeated a plurality of times (page 258, column 2). Further, training sets consisted of eight normal samples and eight unknown samples. Training results on different subregions were assessed and aggregated for a consensus based upon majority scores (page 260, column 2).

Somorjai et al. do not teach the use of this method for identification and classification of bacterial species (present in claims 6-9, 24-27, 35, 36, 42-45, 53, and 54), however, Delpassand et al. et al. do show that NMR is a useful technique to rapidly identify pathogens, including bacteria, by providing a “fingerprint” within the proton spectrum (see entire article). It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the method and classifier of Somorjai et al. to identify and classify bacteria (as was shown by Delpassand et al. to be distinguishable through NMR spectra). One would have been motivated

to do so because Somorjai et al. explicitly state that, although the example in the paper is directed to the identification of thyroid neoplasms, it could be used for any biomedical data. They state that "we introduce and apply a new classification strategy called computerized consensus diagnosis. Its purpose is to provide a robust, reliable classification of biomedical data (see abstract)".

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

September 27, 2004

Lori A. Clow, Ph.D.

Art Unit 1631

Lori A. Clow

MARJORIE MORAN
PATENT EXAMINER

Marjorie A. Moran
9/28/04